

REMARKS

Claims 15-16, 18-20, 38, 41-42, 52-54, 56, 60-61, 69, and 71-74 are currently pending. Support for new claim 71 is found in the Specification, for example on page 49, lines 4-5.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1-4, 12-16, 18-20, 38-42, 57-60 and 62-70 were rejected as failing to comply with the written description requirement. In particular, the Examiner stated that the Specification does not convey that there is any knowledge as to what the role of asparaginyl endopeptidase is in the immune response and notes that the Specification does not disclose any positive relationship between asparaginyl endopeptidase inhibitors and their ability to inhibit class II presentation of antigen to T cells in a subject. Without acquiescing and solely as to expedite prosecution of the present application, the Applicants have canceled claims related to suppressing or inhibiting the immune response in a patient to facilitate expeditious prosecution of this application.

The Specification provides written support for new claim 71 and dependent Claims 15-16 and 18-20 that disclose methods of suppressing or reducing the processing of a protein antigen by an antigen processing cell with an asparaginyl endopeptidase (AEP). For example, the disclosure in Example 1 provides conclusive evidence that inhibitors of AEP reducing the processing of a protein antigen (e.g., the tetanus toxin TTCF) by an antigen processing cell. In the experiments described on pages 44-45 of the Specification, freshly isolated peripheral blood mononuclear cells (PBMC) were incubated with TTCF antigen in the continued presence or absence of AEP inhibitors. At different times, the cells were washed, fixed and then co-cultured with different autologous T cell clones to assess expression of different peptide/MHC complexes. In the presence of an active peptide AEP inhibitor, presentation to some clones was either undetectable or profoundly inhibited. Referring to pages 48-49 of the Specification, antigen presentation by EBV-B cells was also inhibited by inhibitors of AEP. In contrast, control peptides unable to inhibit AEP had no effect on antigen presentation by antigen presenting cells. Finally, the inhibitory effects of inhibitor peptide on antigen processing *in vivo* could be overridden by using TTCF-pre-digested *in vitro* by AEP. In conclusion, correct processing of antigens such as TTCP by antigen presenting cells requires cleavage by AEP. Thus, the Specification provides written support for the claimed invention of suppressing or inhibiting antigen processing by an antigen presenting cell by contacting the antigen presenting cell with an inhibitor of AEP.

The claims relating to the pharmaceutical compositions should also be allowable, as they relate to compositions useful for implementing the methods for implementing the methods for which applicants were in complete possession at the time of filing the present specification.

Support for new Claims 72-74 can be found in the claims as originally filed, in particular, Claims 20 and 56. Thus, Applicants were clearly in possession of the subject matter recited in these claims at the time the present specification was filed. Accordingly, these claims are compliant with the written description requirement.

In light of the above amendments and remarks, the claims are in compliance with 35 U.S.C. § 112, first paragraph and removal of the rejection is respectfully requested.

Allowed Claims

Applicants note with appreciation the Examiner's indication that Claims 52-54, 56 and 61 have been allowed.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: 09/646,950
Filing Date: December 8, 2000

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 28 December 2007

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